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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,288	04/02/1999	WOLFGANG TESCHNER	040433/0177	6758

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/254,288

Applicant(s)

TESCHNER ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18, 20-31 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18, 20-31 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The application should be reviewed for errors. Error occurs, for example, in the spelling of "a t" in claim 17, line 3.

The amendment filed 4/30/03 is acknowledged. Claims 14-18, 20-31 and 33-37 are being considered on the merits.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 14-18, 20-31, and 33-37 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 31 are vague and indefinite in that the extent of the "exchange" is not claim designated and cannot be readily ascertained. Is it 1%, 10%, 80%, 100%? In other words, is it "total exchange"? Is the medicament produced citrate-free? If "replacement" is intended, it is recommended that this term be used.

Also the recitation of "optionally" in claims 14 and 31 and claims dependent thereon with respect to the "exchange" of "citrate-bound metals" renders the claim vague and indefinite. "Optionally" appears to pertain to an option regarding when citrate-bound metals should be "exchanged". It cannot be readily ascertained under which circumstances this option is or is not to be exercised. With respect to the argument that "if present" should be the interpretation of "optionally", it is recommended that "if present" be substituted therefor to clarify the invention.

The Teschner Declaration raises issues of confusing regarding the meaning of "non-precipitating conditions" in the present context. The Teschner Declaration at item 5 states that the conditions are "non-precipitating conditions through diafiltration, ultrafiltration or a chromatographic process", which clearly defines the invention intended. Yet the claims are written are devoid of this limitation. It is recommended that this material be claim designated to clarify the invention.

Claim 31 is vague, indefinite and confusing in the recitation of "using as a starting material", since there is no clear antecedent basis for "material" in the context of a medicament. Also, there is no clear correlation with the composition claimed. Even though the medicament is claimed as a product by process, the antecedent basis/intended purpose of the term "using" is uncertain in this context.

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Claims 31 and 36 are confusing in the recitation of “ $\mu\text{g}/1$ ”, wherein the numeral “1” is used rather than “l” for liter. Also claims 33 and 34 fail to find proper antecedent basis in claim 31 for “ $\mu\text{g}/l$ ”, as does claim 37 in claim 36 for 200 “ ng/l ”.

Claim Rejections - 35 USC § 102

Claims 14-17, 20-23, 26, 28, 31, and 33-37 are/remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5561115 [A] for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments and the Teschner declaration filed 9/10/02 have been fully considered but they are not persuasive.

The arguments and data in the declaration pertain to a comparative Example with the '115 patent. However, results such as a greater yield of protein or greater efficiency are not persuasive of error in the anticipation rejection made, wherein the process steps are the same as claimed. There is no clear correlation between the invention **as claimed** and the results touted. The process steps of the invention as claimed require “exchanging citrate and optionally citrate-bound metals in a plasma-protein containing solution for one selected from the group consisting of a water-soluble monocarboxylate, water-soluble dicarboxylate, a monocarboxylic acid and a dicarboxylic acid under non-precipitating conditions”. This recitation includes, of course, sodium caprylate, as used in the reference.

Applicants argues that in the '115 patent later diafiltration removes citrate, while in the instant invention the use of caprylate and the like under non-precipitating conditions results in efficient displacement of citrate by caprylate and the like. Inasmuch as '115 similarly uses caprylate under non-precipitating conditions to displace citrate at least to some extent, applicant's arguments fail to persuade. The claims as written fail to require a total or complete “exchange” or displacement of citrate. In addition, the exchange process does not have to occur in a one step process which excludes other steps, since the inclusive term “comprises” is used. It is noted that it is at least uncertain when in the process the “non-precipitating conditions” must be applied and for how long.

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Also, in argument, applicants indicate that the medicament provided is "low in citrate" and that a low citrate medicament will not unduly extract undesired metals from glass containers (Response, page 11, paragraph 3). In the comparative examples, citrate content was assessed as < 0.10 mmol/l, which appears suitable for "exchange" of citrate and "optionally of citrate-bound metals". With a such a low content of citrate content it is apparent that the medicament produced by '115 would not "take up any undesired metals when stored in metal-containing containers".

The distinction in the Teschner declaration between "removal" of citrate and "exchange" of citrate is not clear. While the principle of operation of the instant invention may be different, the non-limiting process steps of the invention as claimed read on the reference. The alleged low yield in the reference is noted. However, this does not pertain to an anticipation rejection.

Applicant's contentions regarding the issue lack of mention in the reference of citrate and problems it can cause in metal-containing hard glass, it is noted with all due respect that the claimed invention is directed to the preparation of a medicament and the medicament per se, which are rejected as anticipated.

Therefore the rejection is deemed proper and it is adhered to.

Upon reconsideration and in light of applicant's arguments, the rejection over '997 is no longer maintained.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
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